403(b)(1)(A)(ii), section 410(b) is considered satisfied for plan years beginning before the later of January 1, 1996, or 90 days after the opening of the first legislative session beginning on or after January 1, 1996, of the governing body with authority to amend the plan, if that body does not meet continuously. For purposes of his section, the term "governing body with authority to amend the plan" means the legislature, board, commission, council, or other governing body with authority to amend the plan. See § 1.410(b)-2(d).

(ii) *Other governmental plans.* Any governmental plan described in section 414(d) that is not subject to section 403(b)(12)(A)(i) (nonelective plans) satisfies the requirements of section 410(b) and is treated as satisfying the requirements of section 401(a)(3) as in effect on September 1, 1974, for plan years beginning before the later of January 1, 1996, or 90 days after the opening of the first legislative session beginning on or after January 1, 1996, of the governing body with authority to amend the plan, if that body does not meet continuously. See § 1.410(b)-2(e).

(b) *Regulatory effective dates*—(1) *In general.* Except as otherwise provided in this section §§ 1.410(b)-2 through 1.410(b)-9 apply to plan years beginning on or after January 1, 1994.

(2) *Plans of tax-exempt organizations.* In the case of plans maintained by organizations exempt from income taxation under section 501(a), including plans subject to section 403(b)(12)(A)(i) (nonelective plans), §§ 1.410(b)-2 through 1.410(b)-9 apply to plan years beginning on or after January 1, 1996, to the extent such plans are subject to section 410(b).

(c) *Compliance during transition period.* For plan years beginning before the effective date of these regulations, as set forth in paragraph (b) of this section, and on or after the statutory effective date as set forth in paragraph (a) of this section, a plan must be operated in accordance with a reasonable, good faith interpretation of section 410(b). Whether a plan is operated in accordance with a reasonable, good faith interpretation of section 410(b) will generally be determined based on all relevant facts and circumstances, including the extent to which an employer has resolved unclear issues in its favor. If a plan's classification has been determined by the commissioner to be nondiscriminatory and there have been no significant changes in or omissions of a material fact, the classification will be treated as nondiscriminatory for the relevant plan year. A plan will be deemed to be operated in accordance with a reasonable, good faith interpretation of section 410(b) if it is operated in accordance with the terms of §§ 1.410(b)-2 through 1.410(b)-9.

Par. 24. Section 1.411(d)-4 is amended by revising the sentence at the end of paragraph A-1(b)(1) to read as follows:

§ 1.411(d)-4 Section 411(d)(6) protected benefits.

* * * * *

A-1: * * *

(b) * * *

(1) * * * See § 1.401(a)(4)-4(d) for the definition of an optional form of benefit for plan years beginning on or after January 1, 1994 (or January 1, 1996, in the case of plans maintained by organizations exempt from income taxation under section 501(a), including plans subject to section 403(b)(12)(A)(i) (nonelective plans)).

* * * * *

Par. 25. Section 1.414(r)-1 is amended by revising paragraph (d)(9)(i) to read as follows:

§ 1.414(r)-1 Requirements applicable to qualified separate lines of business.

* * * * *

(d) * * *

(9) * * *

(i) *General rule.* The provisions of this section and of §§ 1.414(r)-2 through 1.414(r)-11 apply to plan years and testing years beginning on or after January 1, 1994 (or January 1, 1996, in the case of plans maintained by organizations exempt from income taxation under section 501(a), including plans subject to section 403(b)(12)(A)(i) (nonelective plans)).

* * * * *

Par. 26. Section 1.414(s)-1 is amended by revising paragraph (i) to read as follows:

§ 1.414(s)-1 Definition of compensation.

* * * * *

(i) *Effective date and transition rules*—(1) *Statutory effective date.* Section 414(s) applies to years beginning on or after January 1, 1987.

(2) *Regulatory effective date*—(i) *In general.* Except as otherwise provided in paragraph (i)(2)(ii) of this section, §§ 1.414(s)-1(a) through (h) apply to years beginning on or after January 1, 1994.

(ii) *Plans of tax-exempt organizations.* In the case of a plan maintained by an organization that is exempt from income taxation pursuant to section 501(a), including plans subject to section 403(b)(12)(A)(i) (nonelective plans), §§ 1.414(s)-1 (a) through (h) apply to plan years beginning on or after January 1, 1996.

(3) *Compliance during transition period.* For plan years beginning before the effective date of these regulations, as set forth in paragraph (i)(2) of this section, and on or after the statutory effective date as set forth in paragraph (i)(1) of this section, a plan must be operated in accordance with a reasonable, good faith interpretation of section 414(s). Whether a plan is operated in accordance with a reasonable, good faith interpretation of section 414(s) will generally be determined based on all relevant facts and circumstances, including the extent to which an employer has resolved unclear issues in its favor. A plan will be deemed to be operated in accordance with a reasonable, good faith interpretation of section 414(s) (1) and (2) if it is operated in accordance with the terms of §§ 1.414(s)-1 (a) through (h). For years beginning before the effective date of these regulations and on or after the statutory effective date, a definition of compensation is also deemed to satisfy section 414(s) as an alternative method of determining compensation under section 414(s)(3) if the definition satisfies the requirements of §§ 1.414(s)-1 (a) through (h) or if the definition satisfies the prior regulation provisions of § 1.414(s)-1T. (See § 1.414(s)-1T as contained in the CFR edition revised as of April 1, 1991.) In addition, for those transition years, a definition of compensation is deemed to satisfy section 414(s) as an alternative method of determining compensation under section 414(s)(3) if, based on all the relevant facts and circumstances in effect for the year, use of the definition does not cause discrimination in favor of highly compensated employees.

Shirley D. Peterson,

Commissioner of Internal Revenue.

[FR Doc. 92-18872 Filed 8-7-92; 8:45 am]

BILLING CODE 4830-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[AD-FDL-4193-1]

RIN 2060-AA96

National Ambient Air Quality Standards for Ozone; Proposed Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed decision.

SUMMARY: In accordance with the provisions of sections 108 and 109 of the

Clean Air Act (Act), as amended, the EPA has conducted a review of the criteria upon which the existing national ambient air quality standards (NAAQS) for ozone (O_3) are based. The revised criteria and supplement are being published simultaneously with the issuance of this proposed decision. The level of the existing primary and secondary standards for O_3 is currently set at 0.12 parts per million (ppm). The standards are attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than 1, as determined by 40 CFR part 50, Appendix H. As a result of the review of health and welfare criteria, the Administrator proposes under section 109(d)(1) that revisions of the primary and secondary standards are not appropriate at this time. In view of ongoing research on the health and welfare effects of O_3 the EPA Plans to proceed as rapidly as possible with the next review of the air quality criteria and standards for O_3.

DATES: The EPA will hold a public hearing on September 1, 1992, 9:30 a.m. to 4:30 p.m. (e.d.t.) Written comments on this proposed decision must be received by October 9, 1992.

ADDRESSES: The public hearing will be held in the EPA Education Center Auditorium, 401 M Street SW., Washington, DC.

Submit comments on the proposed action to: Central Docket Section (A–130), Environmental Protection Agency ATTN: Docket No. A–92–17, 401 M St. SW., Washington, DC 20460. The docket may be inspected between 8 a.m. and 3 p.m. on weekdays, and a reasonable fee may be charged for copying. For availability of related documents, see Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Mr. John H. Haines, MD–12, Air Quality Management Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Telephone: 919–541–5533.

SUPPLEMENTARY INFORMATION:

Public Hearing

Individuals planning to make oral presentations at the hearing should notify John H. Haines, at the above address, at least 7 days prior to the date of the hearing. Oral presentations will be limited to 15 minutes each. Any member of the public may file a written statement before, during, or within 30 days after the hearing. Written statements (duplicate copies preferred) should be submitted to the Central Docket Section, Attention: Docket Number A–92–17 at the address in the **ADDRESSES** section.

Availabilty of Related Information

Certain documents are available from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. Available documents include: Air Quality Criteria for Ozone and Other Photochemical Oxidants (five volumes, EPA 600/8–84–020aF thru eF, August 1986, NTIS No. PB–87–142949, $168.00 paper copy); and the 1989 Staff Paper, Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information (EPA–450/2–92–001, June 1989, NTIS No. PB–92–190446, $43.00 paper copy and $17.00 microfiche). (Add a $3.00 handling charge per order.) The Criteria Document Supplement, Summary of Selected New Information on Effects of Ozone on Health and Vegetation: Supplement to 1986 Air Quality Criteria for Ozone and Other Photochemical Oxidants (EPA/600/8–88–105F) is available at no cost from The Center for Environmental Research Information (CERI), telephone (513) 569–7562. A limited number of copies of other documents generated in connection with this standard review, such as documents pertaining to control techniques for volatile organic emissions from stationary sources, are available and can be obtained from: U.S. Environmental Protection Agency Library (MD–35), Research Triangle Park, NC 27711, telephone (919) 541–2777. These and other related documents are also available in the EPA docket identified in the **ADDRESSES** section.

The contents of today's preamble are listed in the following outline.

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I. Background

A. Legislative Requirements

1. The Standards

Two sections of the Act govern the establishment and revision of NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify pollutants which "may reasonably be anticipated to endanger public health and welfare" and to issue air quality criteria for them. These air quality criteria are to accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of a pollutant in the ambient air.

Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate "primary" and "secondary" NAAQS for pollutants identified under section 108. Section 109(b)(1) defines a primary standard as one the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria and allowing an adequate margin of safety, is requisite to protect the public health. A secondary standard, as defined in section 109(b)(2), must specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on the criteria, is requisite to protect the public welfare from any known or anticipated adverse affects associated with the presence of the pollutant in the ambient air. Welfare effects as defined in section 302(h) [42 U.S.C. 7602(h)] include, but are not limited to, effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.

The U.S. Court of Appeals for the District of Columbia Circuit has held that the requirement for an adequate margin of safety for primary standards was intended to address uncertainties

associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association* v. *EPA*, 647 F.2d 1130, 1154 (D.C. Cir. 1980), *cert. denied*, 101 S. Ct. 621 (1980); *American Petroleum Institute* v. *Costle*, 665 F.2d 1176, 1177 (D.C. Cir. 1981), *cert. denied*, 102 S. Ct. 1737 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, by selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that he finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In selecting a margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. Given that the "margin of safety" requirement by definition only comes into play where no conclusive showing of adverse effects exists, such factors, which involve unknown or only partially quantified risks, have their inherent limits as guides to action. The selection of any numerical value to provide an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association* v. *EPA, supra*, 647 F.2d at 1161–62.

Section 109(d)(1) of the Act requires that "not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards and shall make such revisions in such criteria and standards as may be appropriate. Section 109(d)(2)(A) and section 109(d)(2)(B) require that a scientific review committee be appointed and provide that the committee shall complete a review of the criteria and the national primary and secondary ambient air quality standards and shall recommend to the Administrator any revisions of existing criteria and standards as may be appropriate.

The process by which the EPA has reviewed the existing air quality criteria and standards for O_3 under section 109(d) is described in a later section of this notice.

2. Related Control Requirements

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under title I of the Act (42 U.S.C. 7410), States are to submit, for EPA approval, State implementation plans (SIP's) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with the EPA, also administer the prevention of significant deterioration program (42 U.S.C. 7470–7479) for these pollutants. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants through the Federal Motor Vehicle Control Program under title II of the Act (42 U.S.C. 7521–7574, which involves controls for automobile, truck, bus, motorcycle, and aircraft emissions; the new source performances standards under section 111 (42 U.S.C. 7411); and the national emission standards for hazardous air pollutants under section 112 (42 U.S.C. 7412).

B. Existing Standards for Ozone

The principal focus of this standard review is on the health and welfare effects of O_3. Ozone produced in the ambient air is commonly referred to as tropospheric O_3. It is chemically identical to stratospheric O_3, which is produced miles above the earth's surface and provides a protective shield from excess ultraviolet radiation. In contrast, tropospheric O_3 produces harmful effects due to its oxidative properties and its proximity to humans, plants, and materials. Ozone is not emitted directly from mobile or stationary sources but, like other photochemical oxidants, commonly exists in the ambient air as an atmospheric transformation product. Ozone formation is the result of chemical reactions of volatile organic compounds (VOC's), nitrogen oxides (NO_x, and oxygen (O_2) in the presence of sunlight and generally at elevated temperatures.

Ozone is a highly reactive gas which at sufficient concentrations can produce a wide variety of harmful effects. At elevated concentrations, O_3 can adversely affect human health, vegetation, materials, economic values, and personal comfort and well-being. Hourly average ambient O_3 levels range from 0.03 ppm in the most remote rural areas to 0.30 ppm and higher in the most polluted urban areas. A detailed discussion of formation, concentrations, and effects of O_3 can be found in the 1986 Air Quality Criteria Document (U.S. EPA, 1986), the Criteria Document Supplement (U.S. EPA, 1992), and the Staff Paper (U.S. EPA, 1989).

On April 30, 1971, the EPA promulgated primary and secondary NAAQS for photochemical oxidants under section 109 of the Act (36 FR 8186). These were set at an hourly average of 0.08 ppm total photochemical oxidants not to be exceeded more than 1 hour per year. On April 20, 1977, the EPA announced (42 FR 20493) the first review and updating of the 1970 Air Quality Criteria Document for Photochemical Oxidants in accordance with section 109(d)(1) of the Act. In preparing the Air Quality Criteria Document, the EPA provided a number of opportunities for external review and comment. The EPA made two drafts of the document available for public comment, and these drafts were peer reviewed by the Subcommittee on Scientific Criteria for Photochemical Oxidants of the EPA Science Advisory Board. The EPA published the final revised Air Quality Criteria for Ozone and Other Photochemical Oxidants on June 22, 1978.

Based on the 1978 revised Air Quality Criteria Document and taking into account the advice and recommendations of the Subcommittee, on June 22, 1978, the EPA proposed (43 FR 16962) revisions to the then-current primary and secondary NAAQS for photochemical oxidants. The proposed changes included raising the primary standard to 0.10 ppm, retaining the 0.08 ppm secondary standard, changing the chemical designation of the standards from photochemical oxidants to O_3, and switching to standards with a statistical (i.e., expected exceedances) form rather than a deterministic form (i.e., not to be exceeded more than x number of times per year).

After taking into account public comments, the EPA announced its final decision on the proposed revisions to the 1971 standards. On February 8, 1979 (44 FR 8202), the final rulemaking revised the level of the primary standard from 0.08 ppm to 0.12 ppm, set the secondary standard identical to the primary standard, changed the chemical designation of the standards from photochemical oxidants to O_3, and revised the definition of the point at which the standard is attained to "when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than one as determined by Appendix H."

C. Review of Air Quality Criteria and Standards for Ozone and Other Photochemical Oxidants

In response to requirements of section 109(d) of the Act, on March 17, 1982 (47 FR 11561), the EPA announced that it was undertaking plans to revise the existing 1978 Air Quality Criteria Document for Ozone and Other Photochemical Oxidants and on August 22, 1983, announced (48 FR 38009) that review of primary and secondary standards for O_3 had been initiated. The EPA provided a number of opportunities for review and comment on revised chapters of the Air Quality Criteria Document by organizations and individuals outside the Agency. On November 24, 1982 (47 FR 53119), the EPA announced that its Environmental Criteria and Assessment Office (ECAO) would conduct a public workshop on December 15-17, 1982 for authors and scientific peer reviewers to discuss working draft chapters of a third revision of the Air Quality Criteria Document pertaining to effects of O_3 and other photochemical oxidants on vegetation and materials damage. The EPA announced (48 FR 50157) that a second public workshop to discuss draft chapters on health effects of O_3 was to be held on November 16–18, 1983. The EPA carefully considered comments made at both workshops in preparing the first external review draft, made available (49 FR 29845) on July 24, 1984 for a 90-day public review. On August 6, 1984 (49 FR 31337), the Agency extended the comment period to November 19, 1984. Due to the length and complexity of the document and requests for more time to review it, on November 1, 1984, the Agency further extended the comment period to January 4, 1985 (49 FR 44019).

On February 13, 1985 (50 FR 6049) and on April 2, 1986 (51 FR 11339), the EPA announced two public meetings of the Clean Air Scientific Advisory Committee (CASAC) to be held on March 4–6, 1985 and on April 21–22, 1986, respectively. At these meetings, the CASAC reviewed external review drafts of the Air Quality Criteria Document for Ozone and Photochemical Oxidants. Many individuals and representatives of organizations provided comments for consideration. The EPA placed transcripts of the CASAC meetings in the docket for the 1986 Air Quality Criteria Document (ECAO–CD–81–1). The EPA considered comments received from the public and the CASAC members in preparing the final document. The CASAC sent the Administrator a "closure letter" dated October 22, 1986 indicating that it was satisfied with the final draft of the Air Quality Criteria Document. The letter outlined key issues and recommendations; it is in the docket for today's decision (A–92–17). The EPA released the five-volume 1986 draft final Air Quality Criteria Document in August 1986.

After the CASAC meeting on March 4–6, 1985, the EPA's Office of Air Quality Planning and Standards (OAQPS) began work on the first draft of the Staff Paper (Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information—OAQPS Staff Paper). (The Staff Paper is an assessment of scientific and technical information contained in the 1986 draft final Air Quality Criteria Document and other related exposure and risk assessment documents, and it presents staff recommendations to the Administrator regarding primary and secondary standards.) At a public meeting on April 21–22, 1986, the CASAC reviewed the first draft of the Staff Paper. The CASAC recommended prior to closure that OAQPS staff consider new information on prolonged exposure effects of O_3 in a second draft of the Staff Paper. The CASAC reviewed this second draft in a public meeting of the CASAC held on December 14–15, 1987. Staff of the EPA's Health Effects Research Laboratory (HERL) and Corvallis Environmental Research Laboratory (CERL) made presentations on new and emerging information on health effects of prolonged exposures to O_3 and on alternative indicators of impacts on crops. The CASAC concluded that sufficient new information existed to recommend incorporation of relevant new information into a supplement to the 1986 Air Quality Criteria Document (Supplement) and in a third draft of the Staff Paper.

In early 1988, the EPA began working concurrently on a Supplement and a third draft of the Staff Paper. The ECAO staff prepared a draft Supplement titled "Summary of Selected New Information on Effects of Ozone on Health and Vegetation: Draft Supplement to Air Quality Criteria for Ozone and Other Photochemical Oxidants." The EPA made available copies of both the draft Staff Paper and draft Supplement to the CASAC and the public in November 1988.

The CASAC held a public meeting on December 14–15, 1988 to review the draft Supplement and draft Staff Paper. Major issues included: the definition of adverse health effects of O_3, the significance of health studies suggesting that exercising individuals exposed for 6 to 8 hours to O_3 levels at or below 0.12 ppm may experience transient decreases in pulmonary indicators (including increases in symptom rates), the possibility that chronic irreversible effects may result from lifetime exposures to elevated levels of O_3, and the importance of considering analyses which indicate agricultural crop damage may be better defined by a cumulative seasonal average than by a 1-hour peak level of O_3. In its "closure letter" of May 1, 1989 (reprinted as Appendix I to this notice), the CASAC indicated that the draft Supplement and draft Staff Paper "provide an adequate scientific basis for the EPA to retain or revise primary and secondary standards for ozone." The CASAC concluded that it would be some time before enough new information on the health effects of multihour and chronic exposure to O_3 would be published in scientific journals to receive full peer review and, thus, be suitable for inclusion in a criteria document. The CASAC further concluded that such information could better be considered in the next review of the O_3 standards. The CASAC also noted that the form of the secondary standard was of critical importance in protecting against O_3 effects on vegetation and that a cumulative seasonal average would be more appropriate than a 1-hour standard. The CASAC went on to add that if a more approriate form could not be developed, the Committee was of the opinion that serious consideration be given to lowering the secondary standard to 0.10 ppm. The CASAC strongly endorsed the need for accelerated and expanded research related to multiple hour, seasonal, and lifetime human exposures to O_3, as well as research related to effects of O_3 on forests and ecosystems.

D. Decision Docket

On March 17, 1992, the EPA created a docket (Docket No. A–92–17) for this proposed decision. The docket incorporates by reference the standard review docket (Docket No. OAQPS A–83–04), created in 1983, and the separate docket established for criteria document revision (Docket No. ECAO–CD–81–1), created in 1981.

E. Pending Litigation

On October 22, 1991, the American Lung Association and other plaintiffs filed suit under section 304 of the Act to compel the EPA to complete its review of the criteria and standards for O_3 under section 109(d)(1) of the Act. *American Lung Association* v. *Reilly*, No. 91–cv–4114 (JRB) (E.D.N.Y.). The

U.S. District Court for the Eastern District of New York subsequently issued an order requiring the EPA to sign a **Federal Register** notice announcing its proposed decision on whether to revise the standards for O_3 by August 1, 1992 and to sign a **Federal Register** notice announcing its final decision by March 1, 1993. The order also requires the EPA to use rulemaking procedures in making the proposed and final decisions.

II. Rationale for Proposed Decision

This proposed decision would complete the EPA's review of information on health and welfare effects of O_3 assembled over a 7-year period and contained in the 1986 Air Quality Criteria Document and its Supplement. This review includes an evaluation of key studies published through early 1989, the 1989 Staff Paper assessment of the most relevant information in these documents, and the advice and recommendations of the CASAC as presented both in the discussion of these documents at public meetings and in the CASAC's 1986 and 1989 "closure letters."

Under section 109(b) of the Act, primary and secondary NAAQS are to be based on the air quality criteria issued under section 108, and the EPA must periodically conduct a "thorough review" of the criteria under section 109(d), taking into account the advice and recommendations of the CASAC, as the basis for periodic decisions on whether revisions of NAAQS are appropriate. When Congress enacted the latter requirement in 1977, it was well aware that implementation of the NAAQS can have profound economic and social, as well as environmental, consequences. Understandably, it required that the Administrator's periodic decisions on whether to revise the NAAQS be based on scientific studies that had been rigorously assessed and incorporated in to air quality criteria, and whose implications for public health and welfare had been carefully considered by both the EPA and the CASAC. In practice, the statutory scheme necessarily involves some delay, often a substantial delay, between completion of a criteria document and a final decision on whether to revise the corresponding NAAQS; studies published after completion of the criteria document are ordinarily considered in the next round of review. Otherwise, review and revision of criteria documents would be an endless process because of the continuous need to incorporate new studies, and decisions on whether to revise the standards would never be made.

In the present case, the Administrator has not taken into account a number of recent studies on the health and welfare effects of O_3. Although the EPA is aware of the results reported in many of these studies and has initiated preliminary evaluations of a number of them, the studies were not assessed in the 1986 Air Quality Criteria Document nor its Supplement, nor have they undergone the rigorous review process, including CASAC review, required to incorporate them into a new criteria document. The EPA estimates that up to 1,000 new studies may be involved. Although a substantially smaller number may prove to be important for decision-making purposes, it would be premature to draw conclusions on either the scientific merit or the ultimate implications of particular studies prior to a rigorous and comprehensive assessment of the studies by the EPA and CASAC. As illustrated by the discussion of key studies in this section and by the contents of the five-volume 1986 Air Quality Criteria Document, its Supplement and the 1989 Staff Paper, the nature of such studies, their findings, and the issues to which they are relevant are highly technical and complex. The process for assessing their scientific merit, their relevance, and their ultimate implications for decision making on the NAAQS, as illustrated by the summary of the current review in Section I.C. above, is correspondingly complex.

As discussed in Section III, the EPA estimates that 2 to 3 years will be necessary to incorporate the new studies into a revised criteria document, to evaluate the significance of the key information for decision-making purposes, to develop staff recommendations for the Administrator, and to provide appropriate opportunities for CASAC review and public comment. Having missed both the 1985 and the 1990 deadlines for completion of review cycles under section 109(d), the EPA believes it would be inappropriate and, indeed, does not have unlimited discretion to delay completion of the current review further for these purposes. See *Environmental Defense Fund* v. *Thomas*, 870 F.2d 892 (2d Cir.), *cert. denied sub nom. Alabama Power Co.* v. *Environmental Defense Fund*, 110 S.Ct. 537 (1989). As a practical matter, there is insufficient time to do so under the court order in the *American Lung Association* case. As discussed in Section III, however, the EPA plans to proceed as rapidly as possible with the next review of criteria and standards for O_3.

Based on the 1986 Air Quality Criteria Document, the subsequent Supplement, and the 1989 Staff Paper, and taking into account the CASAC's advice and recommendations, the Administrator focused on a discrete range of policy options for revising or not revising the current O_3 standards. The options included addressing the following questions:

(1) Is sufficient health effects information available to warrant the replacement (or supplementation) of the current 1-hour primary standard with a new 6- to 8-hour standard to protect against prolonged exposures and to provide additional protection for the most sensitive group(s)?

(2) Is sufficient health effects information available to provide the basis for the establishment of a seasonal or other long-term standard to protect against possible chronic effects in the exposed population?

(3) Should the level of the current 1-hour primary standard be revised from 0.12 ppm to 0.10 ppm?

(4) Should the level of the current 1-hour secondary standard be revised from 0.12 ppm to 0.10 ppm, or should a new seasonal standard be established?

A. The Primary Standard

1. Basis for the Existing 1-Hour Standard

In selecting the level for the current 1-hour primary standard in 1979, the Administrator made judgments regarding lowest reported effect levels, sensitive populations, nature and severity of health effects, and margin of safety. The judgment of the lowest observed effect level was based largely on several human clinical studies. The key study was by DeLucia and Adams (1977), who reported symptoms of discomfort and small but statistically-nonsignificant lung function decrements in vigorously-exercising healthy subjects acutely exposed to O_3 at concentrations as low as 0.15 ppm O_3. The principal sensitive group of concern in setting the 1979 O_3 primary standard was asthmatics, although the EPA recognized that nonasthmatic individuals engaged in exercise are also potentially vulnerable to acutely-irritating effects of O_3. In addition, impaired pulmonary function and symptoms were recognized as the best-documented effects in human clinical studies. More severe effects such as decreased resistance to respiratory infection, induction of chronic respiratory disease, and possible carcinogenic/mutagenic effects also had been reported in animal

toxicology studies, and some limited epidemiology studies raised concern about possible aggravation of preexisting chronic respiratory disease. However, uncertainties regarding these data limited their usefulness.

Finally, in selecting a standard level intended to provide an adequate margin of safety, the Administrator noted that the available quantitative information on human health effects of O_3 was quite limited. For that reason and because the more qualitative information in the health criteria suggested the possibility of adverse effects occurring below 0.15 ppm O_3, the Administrator concluded "that a standard of 0.12 ppm is necessary and prudent unless and until further studies demonstrate reason to doubt that it adequately protects public health."

2. Health Effects Information Since 1979

Since 1979, the available information on health effects caused by acute (1- to 3-hour) exposures to O_3 has expanded greatly. Additional new information on prolonged (6- to 8-hour) exposures began to appear in the scientific literature during the late 1980's and continues to be published at this time. Although some information on chronic effects was available in 1979, a significant body of data from animal studies has been published during the past decade confirming damage in animals caused by chronic O_3 exposures. All key information available up to early 1989 has undergone careful review for incorporation in the 1986 Air Quality Criteria Document, the Supplement, and the 1989 Staff Paper.

a. *Effects of 6- to 8-hour exposure.* Reports of enhanced effects from prolonged exposures to O_3 began to appear in 1985. Lioy et al. (1985) and Spektor et al. (1988a,b) conducted summer camp field studies of children engaged in outdoor activity for periods of several days to weeks, during which they were exposed to ambient O_3 for several hours per day. These studies reported that statistically-significant, short-term pulmonary function decrements, compared to initial baseline values, could be measured even when the O_3 NAAQS were not exceeded. The effects increased with exposure to increasing levels of O_3. Pulmonary function decrements reported in the summer camp studies could be attributed in part to factors such as other pollutants or heat. Moreover, the health significance of pulmonary function decrements of the duration and magnitude reported in these studies is unclear.

Multihour human exposure studies were conducted to assess the effects of prolonged exposure to O_3 alone in a controlled environment. These studies (Folinsbee et al., 1989; Horstman et al., 1988, 1989) exposed subjects engaged in intermittent, moderate to heavy exercise (minute ventilation, $\dot{V}_E$=40 liters/minute; e.g., brisk walking or easy cycling) for 6.6 hours to O_3 levels of 0.08, 0.10, and 0.12 ppm. They reported small but statistically-significant group mean decreases in lung function, measured as forced expiratory volume ($FEV_{1.0}$), at all three exposures compared to filtered air. Respiratory systems (e.g., cough, pain on deep inspiration) increase with increasing O_3 levels. (The exposure protocol was designed to simulate a normal workday for a construction worker.) Again, the public health significance of the reported lung function decrements needs further evaluation.

Biochemical indicators of pulmonary inflammation (i.e., cells and other mediators of a lung inflammatory response) were also reported to increase in healthy subjects exposed for 6.6 hours to 0.10 ppm O_3 while engaging in intermittent, moderate to heavy exercise ($\dot{V}_E$=40 liters/minute) (Koren et al., 1988a). More specifically, this and other research (Koren et al., 1988b,c) demonstrate that cells and soluble mediators suggestive of possible danger to pulmonary tissue are increased as a result of prolonged O_3 exposures. The potential significance of these results lies in the fact that they represent indicators of inflammation in humans and potential for damage in lower airways from prolonged O_3 exposures.

The CASAC "closure letter" of May 1, 1989 stated, "While reaching closure at this time, the Committee did note an emerging data base on the acute health effects resulting from 6–plus hours of O_3 exposure, providing evidence of the possible need for a standard with a 6–8 hour averaging time. However, it was the Committee's view that it would be some time before enough of this developing information would be published in scientific journals to receive full peer review and, thus, be suitable for inclusion in a criteria document. The CASAC concluded such information can better be considered in the next review of the ozone standards." Although the studies cited above are of concern to the EPA, they have not yet been confirmed in other laboratories. Similar research is currently under way in other laboratories and should be available for a subsequent review of air quality criteria. For these reasons, the Administrator concurs with the CASAC that this information should be considered in the next review of the O_3 standards.

b. *Effects of seasonal or chronic exposures.* Evidence concerning possible seasonal or chronic effects of O_3 has accumulated in the animal toxicology literature. Chronic and subchronic effects such as inflammation, structural changes in respiratory tissue, and increased collagen content in the lungs have been reported after exposure to O_3 in the range of 0.12 to 1.0 ppm and higher. Impaired ability to resist respiratory infection has been reported after exposure to 0.10 ppm O_3. Quantitative extrapolation of these effects reported in animals to human health effects remains limited by inadequate knowledge of dosimetry and species sensitivity differences.

Although the 1989 CASAC "closure letter" expressed concern for the possibility that chronic, irreversible effects may result for people exposed to O_3 over a lifetime, the CASAC concluded that such changes have not yet been demonstrated. The CASAC also concluded that "there is not an adequate data base on the effects of multiple hour or seasonal exposures to O_3, especially as regards whether such exposures may produce chronic health effects. This is especially troubling since such long-term exposures to O_3 occur in many parts of the United States and involve many millions of people * * *. It is critical that the data base on health and welfare effects related to multiple hour, seasonal and lifetime exposures of O_3 be increased through an accelerated and expanded research effort."

Several chronic animal studies by the EPA, the National Toxicology Program (NTP), and the Health Effects Institute (HEI) are expected to be available in time for the next O_3 criteria review cycle. Animal toxicology studies at the EPA are assessing the health effects in rats of chronic exposure to O_3, and a cooperative effort between the NTP and the HEI is focused on potential carcinogenic and cocarcinogenic, as well as morphological, effects of chronic O_3 exposures. The EPA, in cooperation with New York University, is also conducting an epidemiological field study to investigate the effects of chronic exposure to O_3 and other irritants on lung function development in healthy young adults. Results of many of the above studies should elucidate some, but not all, of the chronic effects issues in the next criteria review cycle.

c. *Effects of 1- to 3-hour exposures.* The 1986 Air Quality Criteria Document reflected a greatly expanded data base on effects from short-term exposures to O_3 of 1 to 3 hours in healthy individuals. Controlled human exposure studies (McDonnell et al., 1983; Cong et al., 1986)

reported small, but statistically-significant, transient declines in pulmonary function (e.g., reductions in lung volume and air flow), which in some cases were accompanied by symptoms (e.g., cough, chest pain, throat irritation, shortness of breath) during exposures to O_3 in the range of 0.12 to 0.15 ppm. These effects, however, were reported only when subjects engaged in very heavy exercise (V_E=68–89 liters per minute). Such exercise levels typically occur when a person engages in activities like running or cycling. It should be noted, however, that without heavy exercise even the most sensitive subjects will not experience statistically-significant decrements in lung function ($FEV_{1.0}$) at low-level O_3 exposures (around 0.12 ppm after 1 to 3 hours); and furthermore, the magnitude of effects which can be measured at these exposure levels, even with heavy exercise, is not generally considered to be adverse to health. A generally accepted relationship is that for any given individual, the greater the exercise level during exposure to O_3, the greater the short-term pulmonary function response experienced (U.S. EPA, 1986, p. 12–81).

One of the key issues that emerged during review of these and other studies was the high degree of variability in responsiveness between individuals exposed to similar O_3 levels. This was evident from the number of studies (Gibbons and Adams, 1984; Linn et al., 1986; Avol et al., 1984; Schelegle and Adams, 1986) that found no statistically-significant response at exposures (0.12 to 0.15 ppm O_3 and exercise levels (V_E=55 to 86 liters per minute) similar to those in the above-cited studies. In two of these studies (Avol et al., 1984; Linn et al., 1986), statistically-significant changes in $FEV_{1.0}$ began to appear at 0.16 ppm O_3.

Although the group mean lung function decrements may be only 1 to 4 percent for the lower level O_3 exposures, the 1986 Air Quality Criteria Document (U.S. EPA, 1986, p. 12–22) concluded that between 5 and 20 percent of otherwise healthy individuals may be more responsive to O_3 during exercise and, therefore, would be at higher risk to O_3 exposures. For example, McDonnell et al. (1983) analyzed intersubject variability in a study involving 135 healthy young males who were exposed to various O_3 levels (0.12 ppm to 0.4 ppm) during 2 hours of intermittent, very heavy exercise. When the subjects were exposed to 0.18 ppm, the study reported changes in $FEV_{1.0}$ ranging from 0 to −23 percent, with a group mean of −6 percent. Subjects exposed to 0.12 ppm O_3 experienced changes ranging from +7 to −16 percent, with a group mean decrement in $FEV_{1.0}$ of −4 percent. Kulle et al. (1985) exposed each of their 20 subjects to various O_3 concentrations for 2 hours with heavy, intermittent exercise. They reported changes in $FEV_{1.0}$ of +10 to −4 percent, with a group mean of +1 percent at 0.10 ppm O_3. The response increased to +3 to −9 percent (group mean of −1 percent) at 0.15 ppm O_3. At 0.2 ppm O_3, the $FEV_{1.0}$ decrements increased to +3 to −16 percent, with a group mean response of −3 percent. At concentrations below 0.18 ppm O_3, these effects would not be noticed by most healthy individuals. For these studies, the effects experienced by even the most sensitive individuals acutely exposed to 0.12 to 0.15 ppm O_3 ranged from −9 to −16 percent decline in $FEV_{1.0}$ with few, if any, symptoms; these effects would be considered only mild to moderate by many health experts (U.S. EPA, 1989, p. VII–53).

The EPA staff made several other observations regarding health effects from short-term exposures to O_3. Exercise performance is reportedly not affected in very heavily-exercising (V_E=86–88 liters per minute) individuals exposed to 0.12 ppm O_3 for 1 hour. Measurable effects were seen in individuals exposed to levels of 0.18 an 0.24 ppm O_3. At exposures of 0.18 and 0.24 ppm, some subjects were not able to complete the protocol (Schelegle and Adams, 1986; Cong et al., 1986). Increased airway reactivity to brochoconstrictors has been observed in heavily-exercising (V_E=70 liters per minute) individuals after 2-hour exposures to 0.18 ppm O_3 (McDonnell et al., 1987). Increased presence of cells and other mediators of lung inflammation have been reported at 18 hours post exposure in heavily-exercising (V_E=64 liters per minute) subjects exposed for 2 hours to 0.4 ppm O_3 (Koren et al., 1988a,b,c). These studies of inflammatory response prompt concern that repeated or chronic exposures to high levels of O_3 may result in permanent lung tissue damage.

Finally, although epidemiological evidence (Whittemore and Korn, 1980; Holguin et al., 1985; Bates and Sizto, 1987, 1989; Lebowitz et al., 1982, 1983) has suggested that O_3 and other photochemical oxidants may be associated with increased asthma attack rates, excess respiratory hospital admissions, and lung function decrements in asthmatics, uncertainty associated with these data make it difficult to determine a clear cause-effect relationship or an appropriate exposure averaging time for the reported responses.

3. Proposed Decision on the Primary Standard

The Administrator is proposing to determine that revisions of the existing O_3 primary standard are not appropriate at this time. In reaching this proposed decision, the Administrator has fully considered the health effects information assessed in the 1986 Air Quality Criteria Document, the Supplement that updated that information, the 1989 Staff Paper, and the advice and recommendations of the CASAC in its 1989 "closure letter."

The Administrator agrees with the staff and CASAC conclusions that the preliminary information on effects of prolonged exposures to O_3 contained in the 1986 Air Quality Criteria Document and the Supplement is not sufficient to support the establishment of a new 6–8 hour standard to protect against prolonged exposures, or a seasonal or other long-term standard to protect against chronic effects. In reaching this proposed decision, the Administrator recognizes that a number of new studies, particularly on 6–8 hour exposures to O_3, have been published in the scientific literature since completion of the air quality criteria that serve as the basis for today's decision. As discussed in Section III, the EPA intends to proceed with the next periodic review of the air quality criteria as rapidly as possible so that the implications of these new studies can be given early consideration. The Administrator is also mindful that there is research in progress on the chronic effects of O_3 that should become available in the next 1 to 2 years. When this new information has been incorporated into the air quality criteria, a more informed decision can be made as to whether adding a new 6–8 hour standard and/or a seasonal or other long-term standard would be appropriate.

The Administrator also carefully considered the health effects information on short-term exposures to O_3 contained in the 1986 Air Quality Criteria Document and its Supplement. As contrasted to the limited information on health effects of O_3 available in 1979, by 1989 information on 1- to 3-hour exposures had expanded greatly. The EPA staff and the CASAC identified several factors that the Administrator should consider in reaching a decision on whether or not to revise the current primary standard to protect against short-term exposures to O_3. These include: (a) The sensitive populations affected by O_3, (b) the nature and

severity of the effects and (c) the protection afforded by the current standards.

a. *Sensitive populations affected.* There are two groups identified as being at potential risk from acute exposures to O_3 (U.S. EPA, 1986, p. 1–164). As discussed in the 1986 Air Quality Criteria Document, the first is that group in the general population characterized as having preexisting respiratory disease (e.g., asthma or chronic obstructive lung disease). These individuals are not more responsive than healthy individuals in terms of the magnitude of pulmonary function decrements seen at typical exposure levels and durations. The EPA is mindful of possible risks to this group because the impact of O_3-induced responses in their already-compromised respiratory systems may more noticeably impair their ability to function adequately, although this has not been fully investigated. Also, limitations on using such individuals in experimental studies have prevented an adequate assessment of the full range of potential responses to O_3 or their health significance in these individuals.

The second group that may be at increased risk to acute O_3 exposures is that subset of the general population of healthy individuals who show an unusual responsiveness to O_3, and who engage in moderate to heavy exercise during elevated O_3 levels. Exercise increases the amount of O_3 entering the airways and can cause O_3 to penetrate to peripheral regions of the lung where lung tissue is more sensitive. Individuals who are unusually responsive to O_3 experience greater decrements in lung function from exposure to O_3 than the average response of the groups studies. As yet, there are no means to determine in advance which persons will be unusually responsive to O_3, but estimates based on subjects already studied suggest 5 to 20 percent of the general population may show a substantially greater response than average. It is not clear whether these individuals constitute a population subgroup with a specific risk factor or simply represent the upper 5 to 20 percent of the O_3 response distribution (U.S. EPA, 1989, p. III–12).

b. *Nature and severity of effects.* Ozone acts as a pulmonary irritant when it comes into contact with the mucous or surfactant layer lining the respiratory tract. Because O_3 is chemically quite reactive, it tends to react rapidly with the mucous layer, thus causing increased total absorption in the upper airways and a reduction in O_3 reaching the more sensitive tissues deeper in the lungs. Exercise, particularly heavy exercise, will increase the total mass of O_3 inhaled per unit time and will change patterns of O_3 deposition in the lungs, thereby causing responses in persons who otherwise might not be affected.

(1) Respiratory Function Decrements and Symptoms. The principal responses associated with acute exposures to O_3 are respiratory function decrements and symptoms. As discussed above, individuals exposed to lower levels of O_3 (e.g., 0.12 to 0.15 ppm) typically experience only mild and transient functional decrements. The available data also suggest that many responders would experience only mild to moderate reductions in lung function which may be accompanied by symptoms such as cough, chest tightness, pain on deep inspiration, and throat irritation. At levels above 0.15 ppm O_3, reductions in lung function and symptoms become more pronounced.

Most healthy individuals experiencing mild to moderate O_3-induced lung function decrements may not notice such effects due to their substantial reserve capacity; however, individuals who have preexisting respiratory disease or have hyperreactive airways may respond to O_3 exposure sufficiently to restrict normal activity or impair their performance in carrying out tasks. While such possible outcomes are a matter of concern, the staff concluded that the data on individuals with preexisting respiratory disease were limited and should only be considered in developing a margin of safety (U.S. EPA, 1989, p. VII–28).

(2) Decreased Resistance to Respiratory Infection. This effect of O_3 has been demonstrated in experimental animal studies. The biological basis for this response appears to be that O_3 or one of its reactive products impairs or suppresses normal bactericidal functions of the pulmonary defense system components (e.g., alveolar macrophages). This results in prolonging the life of the infectious agent, thus permitting its multiplication and ultimately resulting in death in this animal infectivity model. Because these effects have been reported in several species of animals and are potentially serious, the EPA remains concerned about the possibility of increased susceptibility to respiratory infection in humans in response to ambient O_3 exposures. Quantitative extrapolation of these effects reported in animals to human health effects remains limited by inadequate knowledge of dosimetry and species sensitivity differences.

(3) Pulmonary Inflammation and Structural Changes in Respiratory Tissue. Pulmonary inflammation and structural changes in respiratory tissue have also been a focus of concern. One series of studies (Koren et al., 1988 a,b,c) reported biochemical and cellular indicators of pulmonary inflammation in healthy adult males exposed for 2 hours to 0.4 ppm O_3 during intermittent, heavy exercise ($\dot{V}_E$=70 liters per minute); however, acute exposures involving lower concentrations have not been tested. While these studies of inflammatory response prompt concern that repeated or chronic exposures to high levels of O_3 may result in permanent lung tissue damage, such a linkage has not been fully investigated and, therefore, remains hypothetical.

c. *Proposed decision.* Based on the staff's assessment of the health information discussed above and taking into account the advice and recommendations that the CASAC provided in 1989, the Administrator proposes to determine under section 109(d)(1) that revisions of the existing 1-hour primary standard are not appropriate at this time. The standard level is below those levels where controlled human exposure studies found substantial changes in pulmonary function and symptoms. In reaching this conclusion, the Administrator is mindful that the mean group response observed in the controlled human studies up to 0.15 ppm O_3 would at most be characterized as mild, and that most of the responders within this population of normal healthy individuals reportedly experienced only mild to moderate responses under very heavy exercise. Although there is a difference of opinion among the EPA's scientific advisors as to the significance of decrements in lung function in the range of 10 to 20 percent when accompanied by symptoms, it is the Administrator's judgment that the lesser effects associated with exposure to O_3 in the range of 0.12 ppm to 0.15 ppm observed in the controlled human studies do not constitute adverse effects for purposes of section 109 of the Act.

The Administrator also considered other sensitive population groups whose response to O_3 has not been fully characterized. Although some epidemiology studies considered in the 1986 Air Quality Criteria Document and its Supplement suggest that exposure to O_3 at ambient concentrations may result in the aggravation of asthma and preexisting respiratory disease, the Administrator concurred with the staff view that these studies are limited by uncertainties about individual exposure levels and the role of other pollutants

and, therefore, should not be generalized to the entire population. In addition, although individuals with preexisting lung disease are not more responsive to O_3 than healthy persons, the same small change in pulmonary function may have more impact on people whose lung function is already compromised. While all of these studies suggest that these sensitive groups may be at somewhat greater risk at levels of 0.12 ppm O_3 and higher, compared to normal healthy individuals in controlled human exposure studies, in the Administrator's judgment these studies do not provide a sufficient basis for lowering the existing standard.

As discussed above, the emerging information on 8-hour and chronic or seasonal exposures is also of concern. In view of this, the Administrator considered to what extent attainment of the current standard would reduce 8-hour and longer-term seasonal averages. Air quality relational analyses indicate that multihour averages of O_3 would be reduced if the current 1-hour standard is attained (see U.S. EPA, 1989, Appendix A). As control programs are implemented to reduce 1-hour O_3 peak levels, 8-hour and longer-term seasonal averages also will be reduced because most control strategies aimed at attaining the existing 1-hour standard are not time-of-day specific. Such programs will affect every hour of the day to a greater or lesser extent and, thus, lower the entire distribution of O_3 air quality and not just peak concentrations. As a result, the Administrator believes the major control programs required by the 1990 Clean Air Act Amendments will result in notable progress towards bringing the country into attainment with the existing 1-hour standard and should also lower O_3 levels associated with 8-hour and seasonal averaging periods.

Given the above, and the preliminary nature of the information currently assessed in the air quality criteria on 6- to 8-hour exposures, the Administrator is proposing to determine under section 109(d)(1) that revision of the existing 1-hour NAAQS is not appropriate at this time. The Administrator also intends (1) to proceed as rapidly as possible with assessment of the new studies so that a more informed decision can be made on the need for additional protection from 6- to 8-hour and chronic exposures, and (2) to focus on fully implementing the control programs mandated by the Clean Air Act Amendments of 1990.

For the above reasons, the Administrator proses to determine under section 109(d)(1) that revisions of the existing 1-hour primary standard are not appropriate at this time. As discussed more fully above, this proposed determination is based on the EPA's review of the health effects information contained in the 1986 Air Quality Criteria Document and its Supplement, which includes an evaluation of key studies published through early 1989; the 1989 Staff Paper; and the advice and recommendations of the CASAC on these documents. The Administrator has not taken into account more recent studies on the health effects of O_3, which have not undergone the rigorous and comprehensive assessment, including the CASAC review, necessary to incorporate them into a new criteria document. As discussed previously, it would be premature to draw conclusions on either the scientific merit or the ultimate implications of these studies prior to such an assessment, which could not be completed in the time available under the court order in the *American Lung Association* case.

The Administrator also considered and concurs with the staff recommendations that O_3 should remain as the surrogate for controlling ambient concentrations of photochemical oxidants and that the existing form of the standard should be retained.

B. The Secondary Standard

The Administrator also proposes to determine that revisions of the existing 1-hour secondary standard are not appropriate at this time. The rationale for this action is threefold: (1) the appropriate form and level for a new standard to protect crops and forest ecosystems are difficult to determine, given the data currently reviewed by the CASAC; (2) new research is currently under way to reduce this uncertainty for forest ecosystems; and (3) tightening the current 1-hour standard as an interim measure would provide only marginal improvement because a 1-hour averaging period is not the most appropriate exposure indicator, as discussed below, for the full range of exposures (e.g., long-term, repeated peaks) and will be seriously reconsidered in the next review. Section 109(b)(2) of the Act requires the EPA to set a secondary NAAQS at a level that, in the judgment of the Administrator, is requisite to protect the public welfare from any known or anticipated adverse effects. The term "public welfare," which is defined in section 302(h) of the Act, includes, among other things, effects on soils, water, crops, vegetation, wildlife, visibility, manmade materials, animals, hazards to transportation, and climate, as well as effects on economic values and on personal comfort and well-being.[1]

During the first review of O_3 NAAQS in the late 1970's, the EPA carefully examined the scientific and technical information evaluated in the then-revised air quality criteria concerning O_3-related damage to vegetation, crops, materials, and visibility. As part of this process, the EPA developed a staff assessment entitled "Evaluation of Alternative Secondary Ozone Air Quality Standards." Based on this assessment and other relevant factors, the EPA promulgated a revised secondary standard on February 8, 1979 (44 FR 8202) that was identical to the revised primary standard of 0.12 ppm in all respects. In reaching this decision, the Administrator concluded that a secondary standard more stringent than the primary standard was not necessary to adequately protect public welfare.

The current review has focused mainly on effects of O_3 on agricultural crops and forests. Consideration has also been given to the effects of O_3 on materials and on personal comfort and well-being.

1. Effects of Agriculture and Forests

a. *Effect on crops.* The 1979 decision to revise the secondary O_3 NAAQS resulted largely from a lack of evidence adequate to retain a standard more stringent than the primary. The 1978 Air Quality Criteria Document identified the need for "a set of standard equations that would relate plant response to pollutant concentration and duration of exposure and would also incorporate the effects of all other factors that control the responses of plants." The 1978 Air Quality Criteria Document also recognizes that "Development of such equations requires a data base sufficient to relate a given dose (concentration of pollutant times duration of exposure) of oxidant (e.g., O_3, PAN) to some meaningful plant effect" and that "Such equations are not yet available." (U.S. EPA, 1978, p. 264).

To address this fundamental deficiency, in 1980 the EPA initiated a 5-year research program titled the National Crop Loss Assessment Network (NCLAN) to define the relationships between yields of major agricultural crops and O_3 exposure, to assess national economic consequences

[1] It should be emphasized that the relevant statutory goal is the protection of public welfare, and that effects on soils, water, crops, and so forth, even if negative, do not necessarily constitute "adverse" effects on public welfare for purposes of section 109(b)(2). The finding that an effect is adverse is ultimately a judgment to be made by the Administrator.

of the exposure of major agricultural crops to O_3, and to advance the understanding of the cause-effect relationships that determine crops responses to pollutant exposure. Damage to crops is relevant under section 109(b) to the extent it affects public welfare. The NCLAN research program on crops, completed in 1985, provided valuable exposure-response information on a variety of crops and strengthened the evidence for O_3-induced yield reductions in important commercial crops species.

Because of this, the NCLAN data base became a principal focus of the current assessment of yield reductions in commercially-important crops exposed to O_3. Yield reduction or loss is defined as impairment of, or decrease in, the value of the intended use of the plant. This definition includes reduction in aesthetic values, changes in crop quality, and occurrence of foliar injury when foliage is a marketable part of the plant, as well as loss in weight or bulk.

The EPA has analyzed data from the NCLAN to develop predictive equations relating 7-hour seasonal mean O_3 exposures, the indicator used in the NCLAN studies, to crop yield loss. These analyses suggest that a 10 percent mean yield loss occurs for several species when the 7-hour seasonal mean concentration of O_3 exceeds 0.04–0.06 ppm, that grain crops are generally less sensitive to O_3 than other crops, and that sensitivity differences within a species may be as large as a difference between species. In addition to differences in sensitivity among species and cultivars, the available data also suggest the presence of year-to-year variations in plant responses to O_3 (U.S. EPA, 1989, p. X–7).

The scientific community well recognizes that the NCLAN data provide valuable exposure-response information for a variety of crops. However, the adequacy of the 7-hour seasonal mean as an exposure index has been questioned. This seasonal exposure statistic is based on the mean 7-hour daily concentration measured from 9:00 a.m. to 4:00 p.m. averaged over the growing season. The use of a seasonal mean to characterize exposures implies that all exposures over the course of the daylight period are equally effective in inducing plant responses. Several analyses, however, indicate that constant concentrations have less effect on plant growth responses than variable or episodic exposures at equivalent cumulative doses (Musselman et al., 1983; Hogsett et al., 1985). Thus, it is possible for two sites with the same daytime arithmetic mean O_3 concentration to have different estimated crop reductions (Larsen and Heck, 1984). The 7-hour seasonal mean also fails to account for phenological stages of plant development, the impact of peak concentrations, length of episodes, and days between peaks.

In addition to the NCLAN data, the 1986 Air Quality Criteria Document and 1989 Staff Paper also assessed data on the effects of O_3 on crop yield both under more controlled conditions and under ambient air exposures. Data from the controlled studies generally seem to indicate that O_3 concentrations of 0.10 ppm (frequently the lowest concentration used in the studies) for a few hours a day, over a period of several days to several weeks, induce yield loss of 10–55 percent (U.S. EPA, 1989, pp. X–13—X–15). These studies further demonstrate that peak O_3 concentrations cause an effect. Because these studies were conducted in greenhouses or growth chambers, it is difficult to extrapolate the data to field conditions. However, ambient air exposure studies that have been reviewed also confirm that current ambient O_3 levels in many parts of the country can reduce plant yield for some crops. As the current standard is attained, lesser reductions should occur.

b. *Forest ecosystems.* In addition to effects of O_3 on crops, there is evidence, although regionally limited, that some forest ecosystems have been adversely affected by ambient levels of O_3. Among the susceptible areas are the mixed conifer forests of the San Gabriel and San Bernardino mountain ranges east of Los Angeles, where O_3 has been identified as the agent responsible for the slow decline and death of the ponderosa pine and the injury of the Jeffrey pine. The decline of pines in the mixed conifer forest in the San Bernardino Mountains suggests that a potential consequence of O_3 stress is a change in the successional patterns and composition of the forest (Miller et al., 1982). Oxidant injury of eastern white pine and other native vegetation has also been observed in the Eastern United States (U.S. EPA, 1989, p. X–25). Several studies have attributed reductions in the growth of annual rings in eastern white pine to the exposure of the trees to O_3 over a period of 10 to 20 years (Mann et al., 1980; McLaughlin et al., 1982; Benoit et al., 1982).

Dendrochronological studies of the decline of red spruce in the northeast and of reduced growth rates of red spruce, balsam fir, and fraser fir in central West Virginia and western Virginia, also provide further evidence that the reductions in growth and mortality measurable today probably began at least 20 years ago (Johnson and Siccama, 1983; Adams et al., 1985). In addition, reductions in growth rates of loblolly and short leaf pine have been reported in the piedmont regions of the Southeastern United States (McLaughlin, 1985). The magnitude of the role of O_3 in these cases is unclear.

In regard to these most recent declines in growth, there is currently no agreement as to the trigger factor that precipitated the dieback, mortality, and decreased growth. A number of stresses have been identified, including both natural processes and air pollution (Johnson and Siccama, 1983). Given the regional distribution of O_3 in North America and the frequent occurrence of elevated O_3 concentrations, the potential influence of O_3 on forest ecosystems is of concern. The success and composition of producer species within a community are the keys to "maintaining the integrity of an ecosystem * * *. Any significant alterations in producers, whether induced by O_3 or other stresses, can potentially affect the consumer and decomposer populations of the ecosystem, and can set the stage for changes in community structure by influencing the nature and direction of successional changes * * *" (U.S. EPA, 1986, p. 7–51).

While some of the same plant processes are affected in trees and agriculture crop species, perennial plants, because they live longer, must cope with both short- and long-term stresses, the effects of which can be cumulative, lasting over the years, or can be delayed, not becoming apparent for many years. Likewise, effects can possibly be mitigated through short- or long-term recovery or replacement (U.S. EPA, 1986, p. 7–76). As a result, the permanent vegetation in natural ecosystems receives much greater chronic exposure than the short-lived vegetation that makes up agroecosystems. The single agroecosystem has little resilience to pollutant stress; the natural ecosystem is initially more resistent to pollutant stress because of species diversity, but the longer chronic exposures can disrupt the system. As discussed more fully in the next section, this difference between natural ecosystems and agroecosystems raises a key issue when selecting an appropriate exposure indicator for the secondary standard (U.S. EPA, 1989, p. X–26).

In the CASAC's 1989 closure letter in the 1989 Staff Paper, "the Committee took note of the lack of information on the effects of O_3 on forest ecosystems

and urged support for research to remedy this deficiency."

In response to the CSAAC comments and the deficiencies in the data, the EPA's CERL began a Forest O_3 Research Program to develop a data base on O_3 effects on forests and to review alternative exposure indices for use in formulating an appropriate O_3 secondary standard. The major objectives of the Forest O_3 Research Plan are to (1) Identify the most critical aspects of O_3 exposure dynamics (i.e., level, frequency, duration, time of day) through mechanistic studies of O_3 uptake and the relevance of environmental, genetic and cultural factors; (2) develop exposure-response functions for seedlings, saplings, and mature trees exposed to current and changing O_3 levels and assess the role of size and age in their responses; (3) parameterize a process model of tree growth using the data developed in (1) and (2) to be used in stand-level models to enable prediction of forest or stand-level response to changing O_3 levels; and (4) produce an assessment of risk to forest species of O_3 in the presence of multiple stresses. The long-term chronic exposure research for forest tree species is scheduled to be completed in 1995.

Additional forest tree species O_3 response data will soon be available from several ongoing and future research efforts, including the Southern Commercial Forest Research Program begun under the National Acid Precipitation Assessment Program to look at the combined effects of O_3 and acid rain on forest tree species; the Southern Oxidant Study, which is investigating the atmospheric chemistry behind O_3 formation and the effects of regional O_3 on urban O_3 levels; the 1990 Clean Air Act Spatial Trends Network, which will monitor a suite of atmospheric pollutant levels in a nationwide network; and the Environmental Monitoring and Assessment Program, which will monitor species selected to serve as indicators of forest health to determine the current status of forest ecosystems and determine whether or not changes are taking place.

c. *Averaging times and exposure patterns of concern.* In terms of protecting agricultural crops and forests, research has demonstrated that there are many factors of O_3 exposure dynamics that must be considered when formulating an appropriate exposure index, and thus, specification of an appropriate averaging time and form of a secondary standard is complex. These factors include short-term peaks, long-term chronic exposures, duration between peaks, and diurnal and seasonal timing of peaks. In the initial draft of the 1989 Staff Paper, the EPA staff recommended that consideration be given to setting both a 1-hour and a longer-term secondary standard because the relationship between peak values and seasonal averages was generally not predictable with a high degree of confidence; therefore, the enforcement of a 1-hour standard was not believed to adequately reduce high chronic exposure at a particular location. While the CASAC (1989) endorsed the judgment that repeated peak exposures were critical in eliciting responses in agriculture crops, the CASAC's views regarding the appropriateness of a separate long-term standard were less clear. Instead, the CASAC challenged the EPA to identify a single standard formulation that offered protection from both repeated peaks of concern and long—term exposures. The EPA agreed with the CASAC's recommendation to identify a single standard formulation and as a first step analyzed alternative monthly forms of a secondary standard (U.S. EPA, 1989, Appendix A) based on air quality data. The EPA found that the maximum monthly mean of the daily maximum 1-hour averages related well to both repeated peaks and long-term air quality indicators of concern. However, there are little or no effects data for a monthly exposure period.

Subsequently, researchers at the CERL undertook additional analyses of the NCLAN data set. In an extensive retrospective analysis of NCLAN data, Lee et al. (1988a) fit over 600 single-index and general phenologically weighted cumulative impact (GPWCI) indices to response data from seven crop studies. The criterion established for determining "best" exposure indices was that they display the smallest residual sums of square error when the yield-response data were regressed for the various O_3 exposure indices using the Box-Tidwell model.

Lee et al. (1988a) concluded that the top-performing exposure indices were those that (1) cumulate the hourly O_3 concentrations over time, (2) emphasize concentrations of 0.06 ppm and higher, and (3) place the greatest weight on exposures that occur during the plant growth stage. These findings illustrated the importance of including exposure duration, repeated peaks, and periods of increased plant sensitivity when assessing the impact of O_3 on plant growth. Although peak concentrations should be given greater weight, the authors suggested that lower concentrations were important and should also be included in the calculation of an exposure index.

In response to the CASAC recommendations (CASAC, 1987), Lee et al. (1988b) conducted additional retrospective analyses of the NCLAN data in order to evaluate selected exposure indicators. The results indicated that while the GPWCI indices best related plant response to O_3 exposure, there were other indices that were near optimal. These indices included a sigmoid-weighted integrated index (SIGMOID) centered at 0.062 ppm, which the staff concluded was too complex for use as an ambient air quality standard, and cumulative indices that sum all concentrations of 0.06 (or 0.07) ppm or higher (SUM06 and USM07). These latter indices performed well, suggesting that lower, longer-term ambient O_3 levels are important in triggering plant response and should be included in an exposure index. These results support the conclusions reached by Lefohn et al. (1988) and Lee et al. (1987), who used the NCLAN data and cumulation indices with sigmoid and allometric weights in demonstrating the importance of peak concentrations in determining plant response.

The integrated exposure indices (SUM06 and SUM07) are functions of exposure duration and concentration that relate various yield losses calculated from experimental data to exposure "seasons." Lee et al. (1988c) believe experiments replicated in time and/or space that differ in exposure duration but have the same SUM06 or SUM07 values should produce identical predicted relative yield losses. Because these integrated indices capture key components of exposure, they are more adequate than a 7-hour mean as descriptors of plant response; they are also attractive from a regulator perspective because they are simple and easy to implement.

Lee et al. (1988b) also examined the relationships among the various air quality indicators, in response to the CASAC's interest in finding an indicator that correlates well with short-term peak, multiple peak, and long-term averages. Results indicate that fair to strong associations exist between the two cumulative indices (SUM06 and SUM07) and the peak and mean indices: second highest daily maximum (HDM2) and 7-hour seasonal average (M7). The integrated indices, SUM06 and SUM07, are strongly related to M7 and less related to HDM2, because the relationship between SUM07 and HDM2 falls just below the level defined by the authors (Lee et al., 1988b) as indicative of a strong association. These

results suggest that SUMO6 and SUMO7 have potential for a standard that protects against adverse effects from repeated peak and long-term exposures. It should be noted, however, that this assessment is based solely on agricultural corps because of the lack of information to fully assess forest effects. Crop species are more sensitive to high level, short-term peaks of O_3 than perennial plants, which appear to be affected more by chronic exposures to lower levels of O_3 or a combination of both short-term peaks and long-term exposures. Therefore, it is not clear that exposure indices based only on agricultural crops are appropriate in relating ambient concentrations and exposure to the response of perennial plants.

2. Other Welfare Effects

a. *Materials.* Ozone effects on materials have been studied for the last 3 decades. This broad data base has identified several types of materials that are sensitive to O_3 exposure.

The effects of O_3 on elastomers (e.g., automobile tires, protective electrical coverings, etc.) have been the best documented. Ozone causes elastomers to harden, become brittle or cracked, and lose physical integrity. These effects increase in a dose-related fashion (i.e., the product of concentration and exposure duration) and have been shown to be accelerated by the presence of mechanical stress, high humidity, atmospheric pressure, sunlight, and other pollutants. In response, manufacturers have reformulated their products to withstand greater doses of O_3, thus mitigating the effects of O_3 on elastomers.

The reaction of dyes to O_3 is a complex function of O_3 concentration, relative humidity, the presence of other gaseous pollutants, the type of dye and the resistance of the material in which the dye is incorporated. The degradation of fibers from exposure to O_3 is poorly characterized. In general, most synthetic fibers such as modacrylic and polyester are relatively resistant; and cotton, nylon, and acrylic fibers show variable sensitivities to the gas. Anthraquinone dyes incorporated into cotton and nylon fibers appear to be the most sensitive to O_3 damage.

Paint is another material that has been investigated for O_3 damage. In comparison to other materials, the effect of O_3 on paints is small and has a negligible effect on the useful life of the material coated.

Upon reviewing the available scientific technical information on effects of O_3 on materials, the 1989 Staff Paper concluded that "There appears to be no threshold level below which materials damage will not occur; exposure of sensitive materials to any non-zero concentration of O_3 (including natural background levels) can produce effects if the exposure duration is sufficiently long. However, the slight acceleration of aging processes of materials which occurs at the level of the NAAQS is not judged to be significant or adverse. Consequently, the staff concludes that materials data should not be used as a basis for defining an averaging time and concentration for the secondary standard and that the secondary standard should be based on protection of vegetation." (U.S. EPA, 1989, pp. XI–16 to XI–17). The Administrator agrees wit this staff conclusion.

b. *Personal comfort and well-being.* Effects on personal comfort and well-being, as defined by human symptomatic effects, have been observed in controlled human exposure studies at O_3 levels in the range of 0.12–0.15 ppm for 1–3 hours of exposure at very heavy exercise, and at somewhat lower levels in prolonged human exposure studies (at moderate exercise), and in field studies. These effects include nose and throat irritation, chest discomfort, and cough. As recommended by the CASAC and the EPA staff, these effects have been considered health effects and have been taken into account during the review of the primary standard for O_3.

3. Proposed Decision on the Secondary Standard

As previously noted, the Administrator is proposing to determine under section 109(d)(1) that revision of the existing 1-hour secondary standard is not appropriate at this time. In reaching this proposed decision, the Administrator has carefully considered the welfare effects information assessed in the 1986 Criteria Document and its Supplement, the 1989 Staff Paper assessment, and the advice and recommendations of the CASAC (CASAC, 1989). A principal reason for this proposed decision is the absence of sufficient information in the 1986 Criteria Document and its Supplement to specify a new form, averaging period, and level of a secondary standard. Research currently under way will provide significant information on key aspects of O_3 exposure dynamics that are important for assessing the effects of O_3 on forest ecosystems. When this information becomes available and is incorporated into the air quality criteria during the next review, a more informed judgment can be made as to whether revision of the secondary standard is appropriate.

The Administrator also carefully considered the available information on the effects of O_3 on agricultural crops alone. Although the NCLAN studies have provided extensive data on the effects of O_3 on crops, the appropriateness of the seasonal mean exposure indicator used in these studies has been subject to much criticism during the development of revised air quality criteria. Because of this and the other shortcomings of this exposure index that are discussed above, the direct use of the NCLAN data for standard-setting purposes would be inappropriate. The CASAC recognized this and recommended that retrospective analyses be undertaken in order to identify a more appropriate exposure index that would offer protection from both repeated O_3 peaks of concern and long-term O_3 exposures. While these analyses have identified several indicators that show promise, the Administrator concurs with the staff's view that it would be premature to base a change in the form and averaging time of the secondary standard on the preliminary results presented in the Supplement to the 1986 Criteria Document and the Staff Paper. The CASAC also recognized in its closure letter (CASAC, 1989) that further work would be necessary to develop a more appropriate form and averaging period for the secondary standard.

The Administrator also considered tightening the current secondary standard as an interim measure. Throughout the review of the air quality criteria and staff assessment, however, no consensus was reached on an appropriate range of alternative 1-hour standards. The staff had great difficulty throughout the review in developing and justifying alternative levels below that of the current standard due to the lack of data (U.S. EPA, 1989, p. XI–13). In the end, while the staff relied on the preliminary results of the Lee et al. (1988b) study to conclude that the upper-end of the proposed range (0.12 ppm) offers little protection for vegetation (U.S. EPA, 1989, p. XI–14), the staff also determined that the study was too preliminary to serve as a basis for recommending changes in the form and averaging time of the standard. Even if the results of the Lee study provided a sufficient basis for revising the standard downward from 0.12 ppm to 0.10 ppm, as some have suggested, it is the Administrator's judgment that such a change would provide only marginal improvement because a 1-hour averaging period is not the most

appropriate exposure indicator for the full range of exposures, as discussed above, and will be seriously reconsidered during the next standard review. In the interim, it would have imposed a disproportionate and largely meaningless burden on States to review and make appropriate revisions in applicable SIP's.

Given the above information, the Administrator proposes to determine under section 109(d)(1) that revision of the current secondary standard is not appropriate at this time.

III. Continuing Review of Air Quality Criteria and Standards

As previously noted, a large number of new studies on the health and welfare effects of O_3 have been published in the scientific literature, since completion of the 1986 Air Quality Criteria Document, its Supplement, and the 1989 Staff Paper that serve as the basis for today's decision. Among the most pertinent of the new studies are those which address: The effects of prolonged O_3 exposures in controlled human experiments; the impact of O_3 on susceptible subpopulations (e.g., individuals with preexisting respiratory disease), chronic exposure effects in animals; analysis of indicators of yield loss in agricultural crops; and effects of O_3 on forest tree species.

Because of the potential significance of these studies, as well as other ongoing research efforts, the EPA is planning to proceed as rapidly as possible with the next periodic review of the air quality criteria and standards for O_3. Under the process established in sections 108 and 109 of the Act and refined by the EPA and the CASAC, the EPA will begin by announcing the commencement of the review in the **Federal Register**. After carefully assessing and evaluating the pertinent new studies, the EPA will then prepare a preliminary draft of a revised criteria document and subject it successively to review at expert peer-review workshops, by the public, and by the CASAC. Once the CASAC has reviewed the first external review draft of the revised criteria document, thus providing a preliminary basis for review of the existing standards, the EPA staff will prepare a draft staff paper evaluating the most significant information contained in the draft criteria document and develop recommendations for revisions, if appropriate, to the standards. The first draft of the staff paper and the second external review draft of the criteria document will then be made available for public and CASAC review. Typically at this point, the criteria document is of sufficient quality for the CASAC to reach "closure" and will provide the basis for completing the staff paper that in turn will be reviewed by the CASAC. The CASAC will then submit its advice and recommendations to the Administrator. The overall process will take an estimated 2–3 years. Although the process is lengthy and rigorous, the EPA believes it is both necessary and appropriate given applicable statutory requirements, the volume of material requiring careful evaluation, and the extraordinary environmental, economic, and social importance of O_3 NAAQS.

IV. Federal Reference Method

The EPA is not proposing any revisions to the Federal reference measurement method for O_3 described in appendix D to 40 CFR part 50, as amended on February 18, 1975 (40 FR 7042) and further amended on February 8, 1979 (44 FR 8221).

V. Regulatory and Environmental Impact Analysis

Under Executive Order 12291, the EPA must judge whether an action is a "major" regulation for which a Regulatory Impact Analysis (RIA) is required. The EPA has judged the proposed O_3 NAAQS decision is not a major action because there are no additional costs or environmental impacts as a result of not revising the standards. The EPA, therefore, has deemed unnecessary the preparation of either a RIA or an Environmental Impact Statement.

VI. Impact on Small Entities

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 35 seq., the EPA must prepare initial and final regulatory flexibility analyses assessing the impact of certain rules on small entities. These requirements are inapplicable to rules or other actions for which the EPA is not required by the Administrative Procedure Act (APA), 5 U.S.C. 551 et seq., or other law to publish a notice of proposed rulemaking (5 U.S.C. 603(a), 604(a)). The EPA is following rulemaking procedures in deciding whether to revise the O_3 standards in light of the court order in the *American Lung Association* case and the importance of the issue. Under section 307(d) of the Act, as the EPA interprets it, neither the APA nor the Act requires rulemaking procedures where the Agency decides to retain existing NAAQS without change. Accordingly, the EPA has determined that the impact assessment requirements of the RFA are inapplicable to this proposed decision.

VII. Other Reviews

This proposed decision was submitted to the Office of Management and Budget (OMB) for review. Any written comments from OMB and the EPA written responses to these comments are available for public inspection at the EPA's Central Docket Section (Docket No. A–92–17), South Conference Center, room 4, Waterside Mall, 401 M Street SW., Washington, DC.

List of Subjects in 40 CFR Part 50

Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: August 1, 1992.

William K. Reilly,

Administrator.

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Appendix I

May 1, 1989.

The Honorable William K. Reilly,
Administrator
U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Dear Mr. Reilly: I am pleased to transmit via this letter the advice of the Clean Air Scientific Advisory Committee (CASAC) concerning the National Ambient Air Quality Standards for Ozone. CASAC has reviewed and offered comments directly to EPA staff on the EPA criteria document "Air Quality Criteria for Ozone and Other Photochemical Oxidants (1986)," the draft "Criteria Document Supplement (1988)," and the Office of Air Quality Planning and Standards staff position paper "Review of the National Ambient Air Quality Standards for Ozone. Assessment of Scientific and Technical Information (1988)" and related support documents.

CASAC previously reached closure on the 1986 Criteria Document. At a meeting held on December 14–15, 1988, CASAC came to closure on the "Criteria Document Supplement (1988)" and the 1988 Staff Position Paper and concluded that they provide an adequate scientific basis for EPA to retain or revise primary and secondary standards for ozone. While reaching closure at this time, the Committee did note an emerging data base on the acute health effects resulting from 6-plus hours of ozone exposure, providing evidence of the possible need for a standard with a 6–8 hour averaging time. However, it was the Committee's view that it would be some time before enough of this developing information would be published in scientific journals to receive full peer review and, thus, be suitable for inclusion in a criteria document. CASAC concluded such information can better be considered in the next review of the ozone standards.

CASAC did not reach a consensus opinion on endorsement of the staff position paper recommendation that "the range of 1-hour average ozone levels of concern for standard setting purposes is 0.08–0.12 ppm for a primary standard."

The opinion of the CASAC Ozone Review Committee was divided with regard to the upper range of the standard with eight individuals favoring a range with an upper value of 0.12 ppm, three individuals favored an upper bound in the range of 0.10–0.12 ppm, four individuals favored an upper bound value no higher than 0.10 ppm, and one individual abstained from offering an opinion. Several individuals who supported an upper value of 0.12 ppm as well as all of the other individuals who favored a lower value for the upper end of the range expressed the view that at 0.12 ppm there was little or no margin of safety. As you are aware, the margin of safety is intended to provide protection against adverse effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement. Finally, several members of the subcommittee favored development of a standard with a more statistically robust upper bound on the annual distribution of ozone concentrations rather than reliance on the current expected exceedance form of the standard. While the Committee offers no further advice on what form the Agency should consider, we would caution you against any form which alters the degree of health protection afforded by the current standard.

CASAC had substantial discussion of the issue of what are or are not adverse health effects. This discussion was aided by the presentation of this issue in the staff position paper. Within CASAC there was diversity of opinion; some members felt that healthy individuals experience adverse effects when ozone exposure induced any of the responses categorized as moderate (i.e., >10% decrement in FEV_1 or mild to moderate respiratory symptoms) in the staff position paper, while a few members believed that adverse effects would not be experienced until ozone induced more severe effects (i.e., >20% decrement in FEV_1 and moderate to severe respiratory symptoms). The view of some individuals on this matter was influenced by recognition that resolution of the adverse health effect issue represents a blending of scientific and policy judgments and, thus, we feel it appropriate to inform you of the range of our views on this matter.

Of particular concern to CASAC is the potential for effects arising from exposures to ozone with daily peak concentrations at or near 0.12 ppm for periods of 6–8 hours and with co-exposure to other pollutants. This concern is due to air quality analyses which have shown that even in areas which do not repeatedly exceed the ozone standard, ozone concentrations can remain close to 0.12 ppm for several hours per day for extended periods of time in summer. There was concern based on recent controlled human exposure, epidemiology and toxicology studies, that such prolonged exposures could result in increased respiratory impairment. Further, for people exposed to these ozone concentrations over a lifetime, the possibility that chronic irreversible effects may result is

of concern, although such changes have not been demonstrated.

The Committee noted that the Criteria Document Supplement failed to cite and discuss a group of "ecological" epidemiological studies of the effects of ozone on various measures of human health such as hospitalizations for respiratory illnesses or exacerbation of chronic respiratory problems. Although these studies have obvious limitations in establishing cause and effect relationships, they have certain strengths which can aid in regulatory decision-making. Studies of this type should be discussed and evaluated in future criteria documents as a complementary source of information.

While reaching closure on the staff position paper recommending a 1-hour standard, CASAC urged that the Agency provide increased support for research that will prove an improved scientific basis for evaluating the need for standards with multi-hour or seasonal averaging times. Clearly, the obvious, research on this critical environmental health issue must be supported now in order for results to be available for consideration in the next 5-year review cycle. CASAC has enumerated these research needs in some detail in a September 1987 submission to the Agency. The Committee feels these research recommendation are still valid and should be incorporated as expeditiously as possible into the Agency research program.

CASAC did not reach a consensus opinion on endorsement of the staff position paper recommendation of "a 1-hour averaging time standard in the range of 0.06–0.12 ppm" for a secondary standard. The CASAC Ozone Welfare Effects Subcommittee that considered this matter reached a divided opinion; two favored a range with an upper value of 0.12 ppm, three favored an upper value of less than 0.12 ppm, and five favored an upper value of 0.10 ppm. The Committee noted that the form of the standard was of critical importance in protecting against ozone effects on vegetation. The Committee was of the opinion that a cumulative seasonal standard would be more appropriate than a 1-hour standard and felt that such a standard could be developed. CASAC favored issuance of a cumulative seasonal standard form assuming its development would not further delay the standard setting process. If this form of standard cannot be developed in time for the current review, the Committee is of the opinion that you should give serious consideration to setting a 1-hour secondary standard with a maximum of 0.10 ppm. The Committee took note of the lack of information on the effects of ozone on forest ecosystems and urged support for research to remedy this deficiency.

In closing, I would like to briefly comment on CASAC's failure to reach a consensus as to the appropriate range for setting the ozone standards. This lack of consensus is reflective of major deficiencies in our knowledge regarding health and welfare effects of long-term exposure (beyond a few hours) to ozone. The data base is very large and adequate for knowledgeable individuals to reach agreement on the effects of acute exposure to ozone in the range appropriate for setting a 1-hour standard. However, there is not an adequate data base on the effects of multiple hour or seasonal exposures to ozone, especially as regards whether such exposures may produce chronic health effects. This is especially troubling since such long-term exposures to ozone occur in many parts of the United States and involve many millions of people and thousands of acres of crop and forest lands. As a result, there continues to be concern for the public health and welfare threat which may be posed by chronic exposure to ozone. It is critical that the data base on health and welfare effects related to multiple hour, seasonal and lifetime exposures of ozone be increased through an accelerated and expanded research effort. This must be done so that future considerations of ozone standards will derive from a stronger scientific base.

CASAC recognizes that your statutory responsibility to set standards requires public health policy judgments in addition to determinations of a strictly scientific nature. While the Committee is willing to further advise you on the ozone standards, we see no need, in view of the already extensive comments provided, to review the proposed ozone standards prior to their publication in the Federal Register. In this instance, the public comment period will provide sufficient opportunity for the Committee to provide any additional comments or review that may be necessary.

CASAC would appreciate being kept informed of progress on establishing revised or new ozone standards and plans for research on ozone effects. Please do not hesitate to contact me if CASAC can be of further assistance on this matter.

Sincerely,

Roger O. McClellan,

Chairman, Clean Air Scientific Advisory Committee.

[FR Doc. 18932 Filed 8–7–92; 8:45 am]

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INTERSTATE COMMERCE COMMISSION

49 CFR Part 1002

[Ex Parte No. 246 (Sub-No. 10)]

Regulations Governing Fees For Services Performed In Connection With Licensing and Related Services—1992 Update

AGENCY: Interstate Commerce Commission.

ACTION: Proposed rules.

SUMMARY: In this proceeding, the Commission proposes the 1992 user fee update. The fee increases here result from the implementation of the update formula set forth in 49 CFR 1002.3(d). Because final rules have been adopted in Safety Fitness Policy, 8 I.C.C.2d 123 (1991), the Commission now is proposing to implement the filing fee increases for the permanent and emergency temporary motor carrier operating authority applications and motor carrier finance proceedings which were deferred in Regulations Governing Fees for Services—1990 Update, 7 I.C.C.2d 3 (1990), and Regulations Governing Fees For Services—1991 Update, 8 I.C.C.2d 13 (1991). The Commission also is proposing to eliminate the caps on the fees for rail finance and abandonment proceedings and complaint and complaint-type declaratory proceedings, which were adopted in Regulations Governing Fees For Services—1989 Update, 5 I.C.C.2d 817 (1989).

DATES: Comments must be received by September 9, 1992.

ADDRESSES: Send an original and 10 copies of comments to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Kathleen M. King, 202–927–5493 [TDD for hearing impaired: 202–927–5721].

SUPPLEMENTARY INFORMATION:

The Commission preliminarily concludes that these proposed fee increases will not have a significant economic impact on a substantial number of small entities because the Commission's regulations provide for the waiver of filing fees when the required showing of financial hardship or public interest criteria is established.

This decision will not have a significant impact upon the quality of the human environment or the conservation of energy resources.

Additional information is contained in the Commission's decision. To obtain a copy of the full decision, write, call, or pick up in person from: Office of the Secretary, room 2215, Interstate Commerce Commission, Washington, DC 20423. Telephone: (202) 927–7428. [Assistance for the hearing impaired is available through TDD services (202) 927–5921.]

List of Subjects in 49 CFR Part 1002

Administrative practice and procedure, Common carriers, Freedom of information, User fees.

Decided: July 1, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons, Phillips, and Emmett. Vice Chairman McDonald commented with a separate expression. Commissioner Simmons dissented with a separate expression.

Sidney L. Strickland, Jr.,

Secretary.

For the reasons set forth in the preamble, title 49, chapter X, part 1002, of the Code of